IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

Best Medical International, Inc.	)	
	)	
Plaintiff,	)	
	)	**2:10-cv-1043-TFM**
v.	)	
	)	**Filed Electronically**
Accuray, Inc.	)	
	)	
Defendant.	)	

BEST MEDICAL'S OPENING CLAIM CONSTRUCTION BRIEF

Pursuant to LPR 4.3 and the Second Amended Case Management Order (Dkt. No. 130) entered in this case, Best Medical International, Inc. ("Best Medical"), by and through its attorneys, hereby serves and files its Opening Claim Construction Brief.

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I. INTRODUCTION

The Patent-in-Suit, U.S. Patent No. 6,038,283 ("the '283 Patent"), issued on March 14, 2000 with a priority date of October 24, 1996. The '283 Patent covers a method and apparatus for determining an optimized radiation beam arrangement for applying radiation to a target tumor volume while minimizing radiation to healthy structure volumes in a patient. See, '283 Patent, Abstract and Col. 6:47:52.[1]

Best Medical has asserted independent Claims 25 and 29 against Accuray and its CyberKnife Multiplan® Treatment Planning System. The proposed constructions of Claims 25 and 29 set forth by Best Medical herein are consistent with Federal Circuit and Supreme Court case law, which emphasizes the importance of focusing on the precise language of the claims and the "heavy presumption" in favor of the ordinary meaning of claim language, unless the patentee acting as his or her own lexicographer clearly sets forth a definition of a disputed claim term in the specification or prosecution history.

Best Medical thus relies upon the plain meanings of the claim terms, along with any definitions provided in the specification of the '283 Patent, for the proper constructions of the disputed claim terms. Conversely, Accuray's proposed claim constructions repeatedly attempt to improperly limit the claims by reading embodiments disclosed in the specification into the asserted claims, and by reading limitations recited in non-asserted claims of the '283 Patent into Claims 25 and 29.

II. LEGAL STANDARDS TO BE APPLIED

In *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), the Federal Circuit emphasized the importance of focusing on the precise language of the claims and the intrinsic

[1] A copy of the '283 Patent can be found in the Appendix to Joint Disputed Claim Terms Chart (Dkt. No. 131-1), Exhibit 1.

record in determining the extent of the plaintiff's monopoly. The court stressed, "[it] is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Id.* at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). "The claims are 'of primary importance, in the effort to ascertain precisely what it is that is patented.'" *Id.* (quoting *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876)).

Words of a claim "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art as of the effective filing date of the patent application. *Phillips*, 415 F.3d at 1312-13 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). See also*, CCS Fitness, Inc. v. Brunswick Corp.,* 288 F.3d 1359, 1366 (Fed. Cir. 2002) ("Generally speaking, we indulge a 'heavy presumption' that a claim term carries its ordinary and customary meaning.") The court may look to "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." *Phillips*, 415 F.3d at 1314 (quoting *Innova*, 381 F.3d at 1116). Those sources include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.*

"The claims, of course, do not stand alone. Rather they are part of a fully integrated written instrument, consisting principally of a specification that concludes with the claims. For that reason, claims 'must be read in view of the specification, of which they are a part.'" *Id.* at 1315 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978-79 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370, 116 S. Ct. 1384, 134 L.E.2d 577 (1996)). "In addition to consulting

the specification . . . a court 'should also consider the patent's prosecution history, if it is in evidence.'" *Phillips*, 415 F.3d at 1317 (quoting *Markman*, 52 F.3d at 980).

Although the Federal Circuit has emphasized the importance of intrinsic evidence in claim construction, it has also authorized district courts in some circumstances to consider extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Id*. "It has been long recognized in our precedent and in the precedent of our predecessor court, … that dictionaries, encyclopedias and treatises are particularly useful resources to assist the court in determining the ordinary and customary meanings of claim terms." *Texas Digital Systems, Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed. Cir. 2002). See also, *Teleflex, Inc. v. Ficosa N. Am. Corp.,* 299 F.3d 1313, 1325 (Fed.Cir.2002) ("The ordinary meaning of a claim term may be determined by reviewing a variety of sources, including ... dictionaries and treatises...." (internal citations omitted)); *CCS Fitness, Inc. v. Brunswick Corp.,* 288 F.3d 1359, 1366 (Fed. Cir. 2002) ("[O]ur precedents show that dictionary definitions may establish a claim term's ordinary meaning."); *Optical Disc Corp. v. Del Mar Avionics,* 208 F.3d 1324, 1334-35 (Fed.Cir.2000) ("For such ordinary meaning, we turn to the dictionary definition of the term.").

In determining a term's ordinary meaning, the Court may consult both general and technical dictionaries to aid it in its construction efforts. *Vitrionics,* 90 F.3d at 1584, n.6; *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1578 (Fed. Cir. 1996) (employing definitions from a general dictionary to construe claim terms). The Court "may rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the [intrinsic evidence]." *Phillips,* 415 F.3d 1322-23 (quoting *Vitrionics,* 90 F.3d at 1584, n.6). The most frequently cited

dictionary in the opinions of the Court of Appeals for the Federal Circuit is Webster's New Third International Dictionary. See, Miller, Joseph Scott and Hilsenteger, James A., "*The Proven Key: Roles and Rules for Dictionaries in the Patent Office and the Courts*" (October 5, 2004), http://ssrn.com/abstract=577262.

Where claims are written in a "means-plus-function" format pursuant to 35 U.S.C. §112(6), a two-step analysis is used to construe their meaning. "First, we determine the claimed function. Second, we identify the corresponding structure in the written description that performs that function." *JVW Enterprises, Inc. v. Interact Accessories, Inc*., 424 F.3d 1324, 1330 (Fed. Cir. 2005) (citing *Omega Eng'g, Inc. v. Raytek Corp*., 334 F.3d 1314, 1322 (Fed. Cir. 2003)).

III. DISPUTED CLAIM TERMS

A. Claim 25

1. **An apparatus for determining an optimized radiation beam arrangement**[2] for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising:

Best Medical's Proposed Construction

The preamble of Claim 25 is not limiting and therefore requires no construction. Subject to and without waiver of that position, Best Medical provides the following proposed construction because Accuray has asserted that the preamble of Claim 25 is limiting.

The term "apparatus" has a plain meaning that is readily understood and therefore does not require construction. To the extent that a construction is required, "apparatus" should be construed in accordance with its plain meaning: *a machine, device or system*.

[2] Best Medical's proposed terms for construction are underlined in the headings in this brief, and Accuray's are in bold. The same format was used in the Joint Disputed Claim Terms Chart (Dkt. No. 131).

The term "an apparatus for determining an optimized radiation beam arrangement" should be construed in accordance with its plain meaning: *an apparatus (machine, device or system) for determining an "optimized radiation beam arrangement*" (as construed below).

Argument

The preamble of Claim 25 does not represent a limitation of the claim because the remainder of the claim fully defines the subject matter of the invention, and the preamble is not "necessary to give life, meaning, and vitality" to the claim. See, *Pitney Bowes, Inc. v. Hewlett-Packard Co.,* 182 F.3d 1298, 1305 (Fed. Cir. 1999) (citing *Kropa v. Robie*, 187 F.2d 150, 152 (CCPA 1951)). According to the court in *Kropa,* 187 F.2d at 152, after reviewing some 37 cases that turned on the limiting nature of the preambles to the claims in suit:

> [T]he preamble has been denied the effect of a limitation where ... the claim or [interference] count apart from the introductory clause completely defined the subject matter [of the invention], and the preamble merely stated a purpose or intended use of that subject matter. On the other hand, in those ... cases where the preamble to the claim or count was expressly or by necessary implication given the effect of a limitation, the introductory phrase was deemed essential to point out the invention defined by the claim or count. In the latter class of cases, the preamble was considered necessary to give life, meaning and vitality to the claims or counts.

In the present case, the preamble of Claim 25 states the intended use of the invention: "for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient." Moreover, the feature identified in the preamble ("determining an optimized radiation beam arrangement") is recited elsewhere in the claim. Finally, stating the invention is an "apparatus" with an intended use does not "breathe life, meaning or vitality to the claim." *Kopra, supra*. Accordingly, the preamble is not limiting and requires no construction.

To the extent that the preamble is construed by the Court, the only term that is not found elsewhere in the claim is "apparatus." The term "apparatus" is a term commonly used in patent claim drafting and does not require construction in this case. To the extent that a construction is required, "apparatus" should be construed in accordance with its plain meaning: *a machine, device or system*. The specification of the '283 Patent describes the *system* of the invention (Col. 9:49-52):

> The **system** of the present invention includes an **improved optimized treatment planning system**, which accounts for multiple treatment parameters for both a target and multiple surrounding structure types.

See, '283 Patent, Col. 9:49-52 (emphasis added).

Furthermore, the patent statute, 35 U.S.C. § 101 (emphasis added), lists categories of inventions: "Whoever invents or discovers any new and useful process, ***machine***, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." See also, Webster's Third New International Dictionary, © 1993, p. 102 and Webster's Third New International Dictionary, © 2002, http://www.mwu.eb.com ("apparatus" means "a collection or set of materials, instruments, appliances, or machinery designed for a particular use" and "the complex of instrumentalities and processes by means of which an organization functions or a systematized activity is carried out").[3] If the term "apparatus" requires construction, it should be construed in accordance with its plain meaning, the specification of the '283 Patent and in view of the patent statute as *a machine, device or system*.

[3] Exhibit 1 to Best Medical's Identification of Extrinsic Evidence are the relevant pages from Webster's Third New International Dictionary © 1993 for the terms cited herein. Exhibit 2 contains the printouts for the same terms from the online version of Webster's Third New International Dictionary © 2002. The 2002 online definitions are the same as the 1993 print edition, but are being provided because they are easier to read.

Moreover, to the extent that the entire preamble requires construction, it should be construed as: *an apparatus (machine, device or system) for determining an "optimized radiation beam arrangement*" (as construed below).

In its proposed construction of the preamble, Accuray makes the first of many attempts to improperly import limitations from the specification into the claims. More specifically, Accuray proposes that the apparatus be "a computer configured to use the simulated annealing ("SARP") optimization algorithm…" See, Joint Disputed Claim Term Chart ("Joint Chart") (Dkt. No. 131), p. 1. The Federal Circuit has consistently held that "one of the cardinal sins of patent law – [is] reading a limitation from the written description into the claims." See, *Phillips*, 415 F.3d at 1320 (quoting *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1340 (Fed. Cir. 2001)). To the extent that Accuray argues that the "SARP algorithm" should be read into Claim 25 because SARP is described as a preferred embodiment in the specification of the '283 Patent, such arguments have consistently been rejected by the Federal Circuit. As the Federal Circuit stated in *Phillips*, 415 F.3d at 1323, "although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments." See also, *CCS Fitness*, 288 F. 3d at 1366 ("An accused infringer may overcome this 'heavy presumption' and narrow a claim term's ordinary meaning, but he cannot do so simply by pointing to the preferred embodiment or other structures or steps disclosed in the specification or prosecution history.") The specification of the '283 Patent states:

> While the invention will be described in connection with the preferred embodiment, it **will be understood that it is not intended to limit the invention to that embodiment. On the contrary, it is intended to cover all alternatives, modifications, and equivalents**, as may be included within the spirit and scope of the invention as to be defined by claims to be filed in a non-provisional application.

See, '283 Patent, Col. 51-57 (emphasis added).

Further, the Federal Circuit has consistently applied the doctrine of claim differentiation when construing claims: "[T]here is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant." *Comark Communications, Inc. v. Harris Corp*., 156 F.3d 1182, 1187 (Fed. Cir. 1998) (quoting *Tandon Corp. v. United States Int'l Trade Comm'n,* 831 F.2d 1017, 1023 (Fed.Cir.1987)). The SARP algorithm is **not** recited in Claim 25, but, in fact, is explicitly recited in non-asserted Claims 3, 5, 15, 19, 43 and 45.

Accordingly, Accuray's attempt to read the limitation of the "SARP algorithm" into Claim 25 generally, and into the preamble of Claim 25 specifically, is incorrect and should be rejected.

2. a computer **adapted to computationally obtain a proposed radiation beam arrangement**;

Best Medical's Proposed Construction

The term "computer" does not require construction. To the extent that a construction is required, "computer" should be construed in accordance with its plain meaning: *a programmable electronic device that can store, retrieve, and process data*.

The term "adapted to computationally obtain …" should be construed in accordance with its plain meaning: *the "computer"* (as construed above) *is programmed to obtain a "proposed radiation beam arrangement"* (as construed below).

The term "radiation beam arrangement" means *beam positions around a treatment field and/or an array of beam weights, intensities, or fluence profiles*.

As to the term "a proposed radiation beam arrangement," the term "proposed" does not require construction, particularly in light of the construction of the phrase "radiation beam arrangement." The plain meaning of "propose" is "to put forward for consideration … suggest." To the extent that a construction is required, "proposed radiation beam arrangement" should be construed in accordance with its plain meaning: *a suggested radiation beam arrangement*.

Argument

The term "computer" does not require any construction, and it has not been used in the '283 Patent in any way different from its common usage: *a programmable electronic device that can store, retrieve, and process data.* See, Webster's Third New International Dictionary, © 1993, p. 468 and Webster's Third New International Dictionary, © 2002 ("computer" means "a programmable electronic device that can store, retrieve, and process data"). See also, Webster's Ninth New Collegiate Dictionary, 1988, p. 271 (same).[4]

The specification of the '283 Patent discloses the use of a "computer" as follows: "[A] conventional computer or set of computers, and plan optimization software, which utilizes the optimization method of the present invention." See, '283 Patent, Col. 9:62-64. See also, Col. 12: 45-47 ("A suitable computer is utilized in performing the Plan Optimization step, as well as the other steps of the radiation planning system.") Thus, the specification of the '283 Patent uses the term "computer" in accordance with its plain and ordinary meaning.

Similarly, the phrase "adapted to computationally obtain…" does not require any construction, and it has not been used in the '283 Patent in any way different from its common usage: *programmed to obtain a "proposed radiation beam arrangement"* (as construed below).

[4] The relevant pages from Webster's Ninth New Collegiate Dictionary can be found at Exhibit 3 to Best Medical's Identification of Extrinsic Evidence.

The term "radiation beam arrangement" is described in the '283 Patent as follows: "The optimizer of the present invention computes an optimized treatment plan, or **beam arrangement**, **which should be understood to include either the optimal beam positions around the treatment field, the optimal array of beam weights, or beam intensities, otherwise known as an intensity map or a fluence profile or both**." See, '283 Patent, Col. 9:29-34 (emphasis added). Further, the specification also describes the selection of a proposed radiation beam arrangement: "dividing the radiation delivery into a large number of small beams, each of which hit the target area." See, '283 Patent, Col. 12:31-32. Accordingly, the term "radiation beam arrangement" should be construed as: *beam positions around a treatment field and/or an array of beam weights, intensities, or fluence profiles*.

Finally, Accuray suggests that the entire phrase "a proposed radiation beam arrangement" requires construction. Best Medical suggests that it does not. To the extent the Court decides to construe this phrase, Best Medical proposes that the term "proposed" be given its plain and customary definition: *suggested*. See, American Heritage College Dictionary, 3rd Ed. (1993, 1997, 2000), p. 1097.[5] See also, Webster's Third New International Dictionary, © 1993, p. 1819 and Webster's Third New International Dictionary, © 2002 ("to form or declare a plan or intention" and "to offer for consideration, discussion, acceptance, or adoption"). The term "suggest" can also be defined as "to propose (something) as desirable or fitting." See, Webster's Third New International Dictionary, © 1993, p. 2286 and Webster's Third New International Dictionary, © 2002. Once this is done, the phrase can easily be construed to be: *a suggested radiation beam arrangement.* There is no reason to construe the longer phrases any differently than the terms or phrases that comprise them.

[5] The relevant pages from the American Heritage College Dictionary can be found at Exhibit 4 to Best Medical's Identification of Extrinsic Evidence.

Accuray again improperly attempts to incorporate the "SARP algorithm" into its proposed construction. No "algorithm", let alone a "SARP algorithm", is recited in this disputed claim term. Accuray's attempt to read the "SARP algorithm" embodiment disclosed in the '283 Patent specification into Claim 25 is a classic example of what *Phillips* prohibits. Furthermore, it is evident that when Best Medical intended to include a "SARP algorithm" as a feature of a claim, it did so – see Claims 3, 5, 15, 19, 43 and 45. No such recitation is found in Claim 25, and Accuray's proposed construction violates the well-established doctrine of claim differentiation. See, *Comark Communications, Inc.,* 156 F.3d at 1187. Accuray's proposed construction should therefore be rejected.

3. the computer **further adapted to computationally change the proposed radiation beam arrangement iteratively**

Best Medical's Proposed Construction

The meaning of "computer" should be defined as above.

The term "further adapted to computationally change the proposed radiation beam arrangement iteratively" means: *the "computer"* (as construed above) *is programmed to change the "proposed radiation beam arrangement iteratively"* (as construed below).

The term "change the proposed radiation beam arrangement iteratively" means: *changing, (altering, varying or modifying) the proposed radiation beam arrangement repeatedly*. The term "change" does not require construction. To the extent that a construction is required, "change" should be construed in accordance with its plain meaning: *alter, vary or modify.*

Argument

The overall phrase "further adapted to computationally change the proposed radiation beam arrangement iteratively" requires no additional construction in light of the constructions of the individual terms included within the larger phrase.

The phrase "change the proposed radiation beam arrangement iteratively" requires no additional construction in light of the construction of the phrase "radiation beam arrangement." The other words in that phrase ("change," "proposed" and "iteratively") do not require any construction apart from their plain and ordinary meaning. The term "change" means *alter, vary or modify*. See, Webster's Third New International Dictionary, © 1993, pp. 373-74 and Webster's Third New International Dictionary, © 2002 ("syn. change, alter, vary, modify"). See also, Webster's Ninth New Collegiate Dictionary, Exhibit 3, pp. 225-26. The term "proposed" means *suggested*. See, American Heritage College Dictionary, 3rd Ed. (1993, 1997, 2000), p. 1097. See also, Webster's Third New International Dictionary, © 1993, p. 1819 and Webster's Third New International Dictionary, © 2002. The term "iteratively" means *repeatedly*. See, Webster's Third New International Dictionary, © 1993, pp. 1203 and Webster's Third New International Dictionary, © 2002 ("iterative" means "marked by involving repetition or reiteration or repetitiousness or recurrence" and "serving or tending to repeat").[6]

The specification of the '283 Patent confirms the plain meaning of "iteratively":

> The optimal beam arrangement is arrived at by computationally increasing the proposed beam weight *iteratively*, incorporating cost functions to ensure that an *iterative* change in the beam weight would not result in an unacceptable exposure to the volumes of tissue or other structures being subjected to the proposed dose. At each *iteration*, the dose distribution resulting from the proposed beam selection is compared to a prescribed dose for the tumor volume and surrounding tissue structures.

See, '283 Patent, Co. 9:33-42 (emphasis added).

[6] See also, Webster's Ninth New Collegiate Dictionary, Exhibit 3, p. 643 ("iteration" means "the action or a process of iterating or repeating" and "a procedure in which repetition or a sequence of operations yields results successively closer to a desired result").

No special meaning is afforded these terms in the claims, the specification or the prosecution history. As such, the phrase "change the proposed radiation beam arrangement iteratively" should be construed as *change, (alter, vary or modify) the proposed radiation beam arrangement repeatedly*.

As to this element, Accuray makes yet another attempt to improperly incorporate the "SARP algorithm" into its proposed construction. For the reasons set forth above, Accuray's proposed construction should be rejected.

4. wherein the proposed radiation beam arrangement is changed by **changing the <u>beam weights</u>**

<u>Best Medical's Proposed Construction</u>

The term "beam weights" means: the *beam intensities or dose.*

The term "changing the beam weights" means: *changing (altering, varying or modifying) the beam weights* (as construed above). The term "change" does not require construction. To the extent that a construction is required, "change" should be construed in accordance with its plain meaning: *alter, vary or modify*.

<u>Argument</u>

The term "beam weights" means *beam intensities and dose*. The specification of the '283 Patent describes the <u>beam weights</u> as follows:

> In this example, if a single beam is used, the beam weight, or intensity, at the epicenter 602 would be 78% of the dose at the entrance point 603. If a second beam of equal intensity were directed toward the treatment field from the direction indicated by arrow 610 (FIG. 6B) and placed so that the two beams intersected only at the epicenter 602, the dose at the epicenter 602 would be two times 78%, or 156% of the dose from each respective treatment beam. The cumulative of multiple beams passing through the treatment field from the different entrance paths 600, 610 thereby creates a concentration of dose to occur at the epicenter 602.

See, '283 Patent, Col. 9:17-28. See also, Col. 9:33 and Col 15:49-50.

The phrase "wherein the proposed radiation beam arrangement is changed by changing the beam weights" was added to Claim 25 during prosecution. (See, May 25, 1999 Amendment, Appendix to Joint Disputed Claim Terms Chart, Exhibit 7 (Dkt. No. 131-7) pp. 48-53.)

As set forth in the portion of the specification cited above, beam intensities and dosage correspond to beam weights. This conforms with what is understood by those skilled in the art. In particular, Accuray itself has stated that beam weights and dose are synonymous. In a 2010 article titled "*The CyberKnife® Robotic Radiosurgey System in 2010*," at page 435, Accuray stated:

> The optimal set of relative weighting factors for the candidate beam set (*i.e.,* the dose delivered per beam) is obtained by inverse planning methods that are described later.[7]

As to the phrase "changing the beam weights," this phrase requires no additional construction once the terms "changing" (*altering, varying or modifying*) and "beam weights" (*beam intensities or dose*) are construed.

Again, Accuray improperly attempts to incorporate the "SARP algorithm" into its proposed construction of this element. For the reasons set forth above, Accuray's proposed construction should be rejected.

5. the computer **further adapted to incorporate a cost function at each iteration to approach correspondence** of **partial volume data associated with the proposed radiation beam arrangement to partial volume data** associated with **a pre-determined desired dose prescription**

Best Medical's Proposed Construction

The meaning of "computer" should be defined as above.

[7] A copy of this article can be found at Exhibit 5 to Best Medical's Identification of Extrinsic Evidence.

The term "further adapted to incorporate …" means: *the "computer"* (as construed above) *is programmed to incorporate a "cost function"* (as construed below) *at each iteration or step to approach correspondence of "partial volume data"* (as construed below).

The term "cost function" means: *an analytical determination of whether, when any change is made to the strength of the beams being used to treat the patient, the resultant dose distribution is closer to the result desired by the user*.

The term "a cost function at each iteration" means: *at each iteration or repeated step, a cost function* (as construed above) *is calculated.*

The term "to approach correspondence" does not require construction. To the extent that a construction is required, "to approach correspondence" should be construed in accordance with its plain meaning: *to get closer to*.

The term "partial volume data" means: *what percentage of the volume of a tumor or structure can receive how much dose*.

The term "desired dose prescription" means: *the dosages to be achieved in the target and structure volumes*.

The term "pre-determined" does not need to be separately construed from the phrase "desired dose prescription." To the extent that a construction is required, "pre-determined" should be construed in accordance with its plain meaning: *determined beforehand*.

The term "partial volume data associated with the proposed radiation beam arrangement" means: *the partial volume data* (as construed above) *is associated with the proposed radiation beam arrangement* (as construed above). The phrase "associated with" does not require construction. To the extent that a construction is required, "associated with" should be construed in accordance with its plain meaning: *connected or related to.*

The term "partial volume data associated with the predetermined desired dose prescription" means: *the partial volume data* (as construed above) *is associated with the predetermined desired dose prescription* (as construed above). The phrase "associated with" does not require construction. To the extent that a construction is required, "associated with" should be construed in accordance with its plain meaning: *connected or related to.*

Argument

The terms "computer" and "further adapted" should be construed as set forth above.

The term "cost function" is defined in the specification: "The cost function is an analytical determination of whether, when any change is made to the strengths of the beams being used to treat the patient, the resultant dose distribution is closer to the result desired by the user." See, '283 Patent, Col. 13:1-4. Since the "cost function" is specifically defined in the specification, it requires no further construction. Accuray ignores this definition and attempts to incorporate the equations used in the preferred embodiment. For the reasons set forth above, such an attempt should be rejected.

As to the phrase "a cost function at each iteration," this phrase requires no additional construction once the terms "cost function" and "iteration" are construed, and simply means: *at each iteration or repeated step, a cost function* (as construed above) *is calculated*. Accuray's attempt to read the "SARP algorithm" into this phrase should be rejected for the reasons set forth above.

The phrase "to approach correspondence," requires no construction and should be afforded its plain and ordinary meaning: *to get closer to*. See, Webster's Third New International Dictionary, © 1993, p. 106 and Webster's Third New International Dictionary, © 2002 ("approach" means "to draw nearer to") and Webster's Third New International Dictionary,

© 1993, p. 511 and Webster's Third New International Dictionary, © 2002 ("correspond" means "to to be inconformity or agreement").[8] There is no special definition set forth in the specification that would require a construction outside of the plain and ordinary meaning of this phrase.

Accuray attempts to improperly read such limitations into this basic phrase by incorporating CDVH curves into the claim. As with the SARP algorithm, the CDVH curves are described as a non-limiting embodiment of the invention, and are recited elsewhere in non-asserted independent Claims 1, 14, 18, and 40, as well as non-asserted dependent Claims 2, 10-13, 24, 26, 28, 30, 32, 37, 39, 41, 44 and 47. Notably, this list includes non-asserted dependent Claims 26 and 28, which depend from asserted Claim 25. In addition to improperly attempting to read the CDVH feature from the specification into Claim 25, Accuray's proposed construction ignores the doctrine of claim differentiation.

As with the term "cost function," the terms "partial volume data" and "desired dose prescription" are defined in the specification without reference to any specific embodiment, and Best Medical's proposed constructions are derived from those definitions.

The specification of the '283 Patent describes the partial volume data as: "The partial volume data generally describes what percent of the volume of a tumor or structure can receive how much dose." See, '283 Patent, Col. 10:60-62. The term "partial volume data" thus means: *what percentage of the volume of a tumor or structure can receive how much dose*.

The specification of the '283 Patent describes the desired dose prescription as:

> At each iteration, the dose distribution resulting from the proposed beam selection is compared to a prescribed dose for the tumor volume and surrounding tissue structures.

[8] See also, Webster's Ninth New Collegiate Dictionary, Exhibit 3, pp. 98 and 283, respectively.

See, '283 Patent, Col. 9:40-42. See also, FIG. 2, step 802 and Col. 9:55-58 and FIG. 5A ("Goal (Gy)" and "Limit (Gy)").

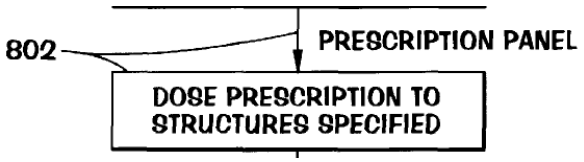


FIG. 5A

Planning Goals

Number of fractions 39 over 50 days (inclusive)

Deliver all table angles in each fraction

Load Planning Set

Load Planning Set

Target Name	Bd	Goal (Gy)	Vol Below Goal (%) Bv	Min (Gy) A	Max (Gy) C
Target 1	☒	75.0	5	70.0	80.0
Target 2	☐				
Target 3	☒				

Sensitive Structure Name		Limit (Gy) Bd'	Vol Above Limit (%) Bv'	Min (Gy) A'	Max (Gy) C'	BU	BP
Tissue	☐	70.0	20	0.0	80.0	☑	☐
Brain Stem	☒	Bd' 55.0	Bv' 10	A' 50.0	C' 60.0	☐	☑
Spinal Cord	☒	Bd' 50.0	Bv' 20	A' 45.0	C' 60.0	☐	☑
Larynx	☒					☐	☐
Auditory Apparatus	☒	Bd' 10.0	Bv' 10	A' 50.0	C' 15.0	☑	☐
Esophagus	☒					☐	☐
Trachea	☒					☐	☐
Parotid Gland	☒	35.0	Bv' 50	A' 30.0	C' 70.0	☑	☐
Thyroid Gland	☐	Bd' 55.0	Bv' 10	A' 45.0	C' 60.0	☐	☑
Ref 1	☒	Bd' 70.0	Bv' 90	A' 55.0	C' 80.0	☑	☐
Brain	☒					☐	☐
Lymph Node(s)	☒					☐	☐
Orbits	☒	Bd' 55.0	Bv' 10	A' 45.0	C' 65.0	☑	☐
Tissue-equivalent	☒					☐	☐
External Avoidance	☒					☐	☐

The term "desired dose prescription" thus means: *the dosages to be achieved in the target and structure volumes*. Accuray's attempts to incorporate CDVH curves and the SARP algorithm is not only improper but unnecessary in light of the definitions provided in the specification.

As to the phrase "a pre-determined desired dose prescription," it requires no further construction once the term "desired dose prescription" is construed and the word "pre-determined" is given its plain and ordinary meaning: *determined beforehand*. See, Webster's Third New International Dictionary, © 1993, p. 1786 and Webster's Third New International Dictionary, © 2002 ("predetermine" means "to determine beforehand").[9] Accuray does not

[9] See also, Webster's Ninth New Collegiate Dictionary, Exhibit 3, p. 926.

provide a suggested construction of this phrase by itself, but only as part of the larger phrase "partial volume data associated with the predetermined desired dose prescription."

As to the terms partial volume data associated with the proposed radiation beam arrangement and partial volume data associated with the predetermined desired dose prescription, the specification states:

> In the system of the present invention, partial volume data are entered by the user during the Prescription Panel step 802 (FIG. 2). FIG. 5 shows an embodiment of a prescription panel 400 used to input the partial volume data into the planning system of the present invention. The partial volume data generally describes what percent of the volume of a tumor or structure can receive how much dose.

See, '283 Patent, Col. 10:55-62.

> FIG. 5 shows an embodiment of a prescription panel 400 used in the Prescription Panel step 802 of the present invention in which numerical values are entered for the partial volume data for each target and structure.

Id., '283 Patent, Col. 12:21-24.

With respect to the phrase "partial volume data associated with the proposed radiation beam arrangement," this phrase is easily construed based upon the construction of its component terms and phrases and the plain meaning of the term "associated with." As suggested by Best Medical, this phrase should be construed as: *the partial volume data* (as construed above) *is associated with the proposed radiation beam arrangement* (as construed above). The term "associated with" does not require construction, and should be construed in accordance with its plain meaning: *connected or related to.* See, Webster's Third New International Dictionary, © 1993, p. 132 and Webster's Third New International Dictionary, © 2002 ("associate" means "to

join (things) together or connect (one thing) with another" and "to join or connect in any of various intangible or unspecified ways").[10]

Similarly, the phrase "partial volume data associated with the predetermined desired dose prescription," is easily construed based upon the construction of its component terms and phrases and the plain meaning of the term "associated with." As suggested by Best Medical, this phrase should be construed as: *the partial volume data* (as construed above) *is associated with the predetermined desired dose prescription* (as construed above).

Again, Accuray attempts to improperly incorporate the SARP algorithm, and further attempts to improperly incorporate the CDVH curves, into its proposed construction. For the reasons set forth above, Accuray's proposed construction should be rejected.

6. the computer further adapted to reject **the change of the proposed radiation beam arrangement** if the change of the proposed radiation beam arrangement **leads to a lesser correspondence to the desired dose prescription** and to accept the change of the proposed radiation beam arrangement if **the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription**

Best Medical's Proposed Construction

The meaning of "computer" should be defined as above.

The term "further adapted to reject ..." should be construed in accordance with its plain meaning: *the "computer"* (as construed above) *is programmed to reject the "change of the proposed radiation beam arrangement ..."* (as construed above).

The term "the change of the proposed radiation beam arrangement" should be defined as above.

[10] See also, Webster's Ninth New Collegiate Dictionary, Exhibit 3, p. 110 ("associate" means "closely connected with another" and "closely related esp. in the mind").

The term "leads to a lesser correspondence to the desired dose prescription" should be construed in accordance with its plain meaning: *the "proposed radiation beam arrangement"* (as construed above) *would cause a dosage of radiation that is further from the "desired dose prescription"* (as construed above).

The term "leads to a greater correspondence to the desired dose prescription" should be construed in accordance with its plain meaning: *the "proposed radiation beam arrangement"* (as construed above) *would cause a dosage of radiation that is closer to the "desired dose prescription"* (as construed above).

Argument

The terms "computer," "further adapted" and "the change of the proposed radiation beam arrangement" should be construed as set forth above.

As to the term leads to a lesser correspondence to the desired dose prescription, the specification of the '283 Patent states:

> The optimal beam arrangement is arrived at by computationally increasing the proposed beam weight iteratively, incorporating cost functions to ensure that an **iterative change in the beam weight would not result in an unacceptable exposure to the volumes of tissue or other structures being subjected to the proposed dose**. At each iteration, the dose distribution resulting from the proposed beam selection is compared to a prescribed dose for the tumor volume and surrounding tissue structures**. If the increase or decrease in beam weights would lead to a greater correspondence to the desired prescription, change is accepted**.

See, '283 Patent, Col. 9:33-45 (emphasis added).

The phrase "leads to a lesser correspondence to the desired dose prescription" is easily construed based upon the construction of its component terms and phrases and the plain meaning of the term "lesser correspondence." As suggested by Best Medical, this phrase should be construed as*: The "proposed radiation beam arrangement"* (as construed above) *would cause a dosage of radiation that is further from the "desired dose prescription"* (as construed above).

Similarly, the phrase "leads to a greater correspondence to the desired dose prescription" is easily construed based upon the construction of its component terms and phrases and the plain meaning of the term "greater correspondence." As suggested by Best Medical, this phrase should be construed as: *The "proposed radiation beam arrangement"* (as construed above) *would cause a dosage of radiation that is closer to the "desired dose prescription"* (as construed above).

In attempting to construe the word "correspondence" Accuray provides a lengthy and convoluted definition of a simple and easily understood term. There is no reason to craft such a complicated and confusing definition for the word "correspondence." See, Webster's Third New International Dictionary, © 1993, p. 511 and Webster's Third New International Dictionary, © 2002 ("correspond" means "to to be inconformity or agreement").[11]

In addition, Accuray attempts to improperly incorporate CDVH curves into its definition. Further, Accuray unnecessarily incorporates in its proposed construction a new term, "total dose cost", which appears nowhere in the disputed claim term.

For the foregoing reasons, Accuray's proposed construction should be rejected.

7. to obtain an optimized radiation beam arrangement

Best Medical's Proposed Construction

The term "optimized radiation beam arrangement" means: *an arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient.*

Argument

The proposed construction provided by Best Medical is supported by the specification. The "optimized radiation beam arrangement" is described in the specifications as "applying

[11] See also, Webster's Ninth New Collegiate Dictionary, Exhibit 3, p. 293 ("correspond" means "to compare closely")

radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, …." See, '283 Patent, Col. 4:16-18. See also, Col. 3:9-12 ("treatment plans are desired that are optimized to eradicate the tumor volume while minimizing the amounts of radiation delivered to the surrounding structures").

Accuray again attempts to improperly incorporate the SARP algorithm into its proposed construction. As stated above, such an attempt should be rejected. It should be noted that Accuray also incorporates by reference the portions of the intrinsic record it cited for the preamble in support of its construction of this term. This corroborates Best Medical's position that the preamble does not require construction, particularly in light of the fact that the preamble does not set forth any limitations that are not contained in the remainder of the claim.

B. Claim 29

1. **An apparatus for determining an optimized radiation beam arrangement** for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising a computer, including:

Best Medical's Proposed Construction

For the reasons discussed above for Claim 25, the preamble of Claim 29 likewise does not represent a limitation of the claim. Furthermore, to the extent that any construction is required, the meanings of "apparatus," "an apparatus for determining an optimized beam arrangement" and "computer" should be defined as they are for Claim 25.

2. **means for computationally obtaining a proposed radiation beam arrangement**

Best Medical's Proposed Construction

The parties agree that this term should be governed by 35 U.S.C. § 112(6).

Function

The function is computationally obtaining a proposed radiation beam arrangement.

Structure

The corresponding structure includes a computer programmed to computationally obtain a proposed radiation beam arrangement, and equivalents thereof.

The disclosed structure/algorithm is depicted in FIG. 2, step 803 ("PLAN OPTIMIZATION" and "BEAM POSITION AND STRENGTH OPTIMIZATION PERFORMED"), FIG. 5B ("Simulated Annealing Parameters," "Iterations," "Start grain," "Change interval," "kT_0/beam," "End grain," "End threshold" and "Revert to Default"), and the descriptions set forth at Col. 12:27-34; Col. 8:61-67; Col. 9:52-59; Col. 10:43-53.

The structure/algorithm described in the '283 Patent corresponding to the claimed function is set forth below:

> In the Plan Optimization step 803, the radiation plan optimization is a specific case of an inverse problem, where the goal is to determine the best way to achieve the dose prescription. A SARP technique is utilized to do this optimization by dividing the radiation delivery into a large number of small beams, each of which hit the target. The annealing cooling schedule utilized, fits into the class of FSA (Fast Simulated Annealing) techniques.

See, '283 Patent, Col. 12:27-34.

> Simulated annealing radiotherapy planning ("SARP") methods are well known in the art to compute optimized radiation beam arrangements to meet objective parameters of a physician with regard to conflicting treatment objectives of a tumor volume and its surrounding structures. Existing SARP methods utilize systematic algorithms to calculate a proposed, optimized beam arrangement.

Id., '283 Patent, Col. 8:61-67.

> The system includes a modified cost function, which allows a physician to use conventional cumulative dose volume histographs ("CDVH"s) to establish a desired prescription of dosage to both the target volume, or target, and each involved structure volume, or structure, which will then

> be used as input for the system for determining the proposed radiation dose distribution delivery to a patient.

Id., '283 Patent, Col. 9:52-59.

> [T]he familiar CDVH curves 100, 200 are used by a physician using the system of the present invention not only in the Output Process step 807 (FIG. 2), discussed hereinafter in detail, but also prior to the Plan Optimization step 803 (FIG. 2) to establish partial volume data representing dosage limits and other parameters, as hereinafter discussed in detail, for each target and structure to establish the input parameters for the cost function of the present invention, which may be entered in the Prescription Panel step 802 (FIG. 2) of the present invention.

Id., '283 Patent, Col. 10-43-53.

The structure/algorithm can also be found in the figures depicted below:

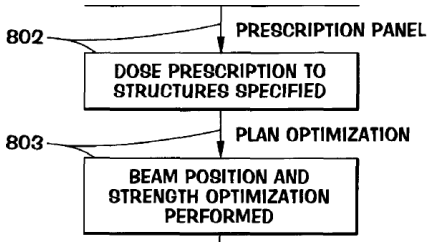


Figure 2

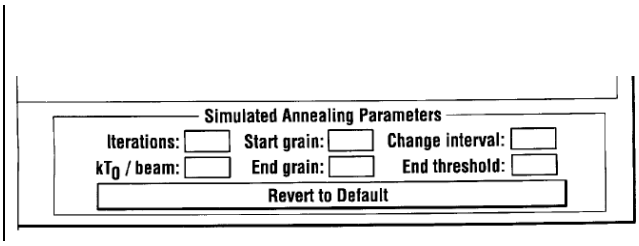


Figure 5B

3. **<u>means for computationally changing the proposed radiation beam arrangement iteratively</u>**, wherein the means for computationally changing the proposed radiation beam arrangement includes

<u>Best Medical's Proposed Construction</u>

The parties agree that this term should be governed by 35 U.S.C. § 112(6).

<u>Function</u>

The function is computationally changing the proposed radiation beam arrangement iteratively.

Structure

The corresponding structure includes a computer programmed to computationally change the proposed radiation beam arrangement iteratively, and equivalents thereof.

The disclosed structure/algorithm is depicted in FIG. 2, step 803 ("PLAN OPTIMIZATION" and "BEAM POSITION AND STRENGTH OPTIMIZATION PERFORMED"), FIG. 5B ("Simulated Annealing Parameters" and "Iterations"), and the descriptions set forth at Col. 9:33-48; and Col. 12:27-47.

The structure/algorithm described in the '283 Patent corresponding to the claimed function is set forth below:

> The optimal beam arrangement is arrived at by computationally increasing the proposed beam weight iteratively, incorporating cost functions to ensure that an iterative change in the beam weight would not result in an unacceptable exposure to the volumes of tissue or other structures being subjected to the proposed dose. At each iteration, the dose distribution resulting from the proposed beam selection is compared to a prescribed dose for the tumor volume and surrounding tissue structures. If the increase or decrease in beam weights would lead to a greater correspondence to the desired prescription, the change is accepted. Ultimately, the SARP method will produce an optimized treatment plan, based on the treatment objectives as expressed by the cost function incorporated in the SARP algorithm

See, '283 Patent, Col. 9:33-48.

> In the Plan Optimization step 803, the radiation plan optimization is a specific case of an inverse problem, where the goal is to determine the best way to achieve the dose prescription. A SARP technique is utilized to do this optimization by dividing the radiation delivery into a large number of small beams, each of which hit the target. The annealing cooling schedule utilized, fits into the class of FSA (Fast Simulated Annealing) techniques.

Id., '283 Patent, Col. 12:27-34.

The structure/algorithm can also be found in Figure 2, step 803 (shown above) and the portion of Figure 5B shown above.

4. **means for changing the beam weights**

Best Medical's Proposed Construction

The parties agree that this term should be governed by 35 U.S.C. § 112(6).

Function

The function is changing the beam weights.

Structure

The corresponding structure includes a computer programmed to change the beam weights, and equivalents thereof.

The disclosed structure/algorithm is depicted in FIG. 2, step 803 ("PLAN OPTIMIZATION" and "BEAM POSITION AND STRENGTH OPTIMIZATION PERFORMED"), FIG. 5B ("Simulated Annealing Parameters," "Iterations," "Start grain," "Change interval," "kT_0/beam," "End grain" and "End threshold"), FIGS. 6A and 6B, and the descriptions set forth at Col. 12:27-34; Col. 13:43-52, Col. 9:13-28; and Col. 14:44 – 14:47.

The structure/algorithm described in the '283 Patent corresponding to the claimed function is set forth below:

> In the Plan Optimization step 803, the radiation plan optimization is a specific case of an inverse problem, where the goal is to determine the best way to achieve the dose prescription. A SARP technique is utilized to do this optimization by dividing the radiation delivery into a large number of small beams, each of which hit the target. The annealing cooling schedule utilized, fits into the class of FSA (Fast Simulated Annealing) techniques.

See, '283 Patent, Col. 12:27-34.

> Thus, the system will reject the change that was made to the beams and will again attempt to change the beam weights to lower the total cost, according to conventional optimization techniques known in the art. Where target goals and structure limits conflict, beam changes will decrease the cost in the target while increasing the cost in one or more of the structures. A determination of whether or not that beam change is kept by the system depends upon the relative changes in the costs of the targets and structures.

Id., '283 Patent, Col. 13:43-52.

> Referring to FIGS. 6A and 6B, by way of example, FIG. 6A shows a dose relationship for the central ray of a single beam directed toward a treatment field from the direction indicated by arrow 600. The three-dimensional treatment field is shown projected on the two-dimensional grid 601. In this example, if a single beam is used, the beam weight, or intensity, at the epicenter 602 would be 78% of the dose at the entrance point 603. If a second beam of equal intensity were directed toward the treatment field from the direction indicated by arrow 610 (FIG. 6B) and placed so that the two beams intersected only at the epicenter 602, the dose at the epicenter 602 would be two times 78%, or 156% of the dose from each respective treatment beam. The cumulative of multiple beams passing through the treatment field from the different entrance paths 600, 610 thereby creates a concentration of dose to occur at the epicenter 602.

Id., '283 Patent, Col. 9:13-28. See also, '283 Patent, Col. 14:44-47 ("A change may be made to a beam which causes a reduction to the target cost. This beam change may cause the area in zone S5 of the CDVH curve for the structure to increase.")

The structure/algorithm can also be found in Figure 2, step 803 shown above, the portion of Figure 5B shown above and in Figures 6A and 6B depicted below:

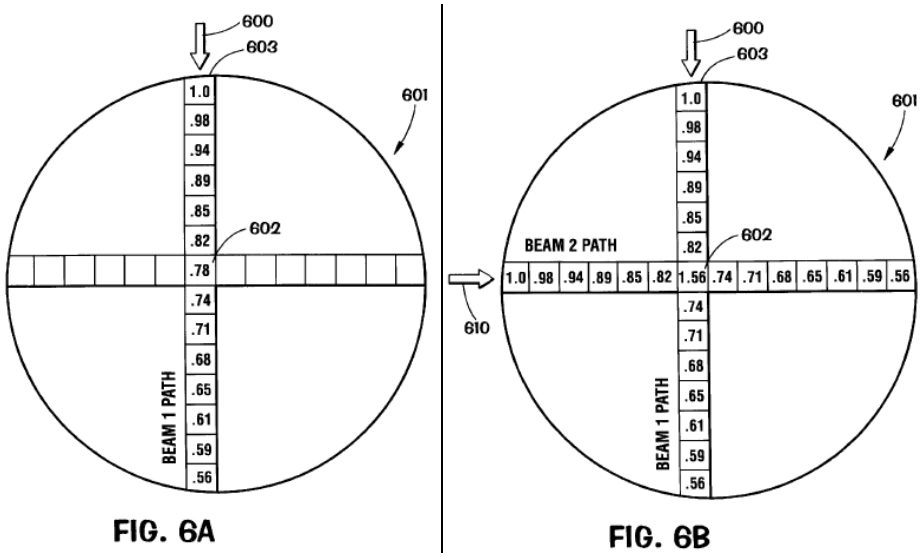


FIG. 6A FIG. 6B

The phrase "wherein the proposed radiation beam arrangement is changed by changing the beam weights" was added to Claim 25 during prosecution. (See, May 25, 1999 Amendment, Appendix to Joint Disputed Claim Terms Chart, Exhibit 7 (Dkt. No. 131-7) pp.48-53.)

5. **means for incorporating a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a predetermined desired dose prescription**

Best Medical's Proposed Construction

The parties agree that this term should be governed by 35 U.S.C. § 112(6).

Function

The function is incorporating a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a predetermined desired dose prescription.

Structure

The corresponding structure includes a computer programmed to incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a predetermined desired dose prescription, and equivalents thereof.

The disclosed structure/algorithm is $C_{Total}=C_S+C_{T,}$ where Cs is the sum of the costs calculated for each structure zone and C_T is the sum of the costs calculated for each target zone, as described in Col. 13:1 – 14:10 and Col. 10:31-34. See also, Col. 4:13 – 5:8; Col. 9:28- 12:67; and Col. 8:61-67. See also, FIG. 2, step 802 ("PRESCRIPTION PANEL" and "DOSE PRESCRIPTION TO STRUCTURES SPECIFIED") and step 803 ("PLAN OPTIMIZATION" and "BEAM POSITION AND STRENGTH OPTIMIZATION PERFORMED"), FIG. 3 (PERCENT VOLUME vs. DOSE (Gy) curve) and FIG. 4 (PERCENT VOLUME vs. DOSE (Gy) curve), FIG. 5A ("Target" entries and "Sensitive Structure" entries) and ("Review the prescription, planning parameters and maximum dose to non-target structures. If all are correct, approve the prescription") and FIG. 5B ((Percent) Volume vs. Dose (Gy) curve and "Simulated Annealing Parameters"). See also, Col. 10:43 – 12:26.

The structure/algorithm described in the '283 Patent corresponding to the claimed function is set forth below:

> The cost function is an analytical determination of whether, when any change is made to the strengths of the beams being used to treat the patient, the resultant dose distribution is closer to the result desired by the user. In the cost function of the present invention, each region, or zone, of the CDVH is assigned a relative weight, according to the importance of that region, or zone, of the CDVH. A zone cost is then calculated for the target and each structure, according to the following formula:
>
> $C_z=W_z*(A_p/A_d)$,

where C, is the cost for the current zone, W_z, is the weight assigned to the current zone, A_p, is the area of the current zone of the proposed CDVH curve, or pseudo-curve, and A_d, is the area of the current zone of the desired CDVH curve except for target zone T7, where A_d is the length represented by target zone T7 and structure zone S8, where A_d is the length represented by structure zone S8. After each zone cost is calculated, the target or structure cost is calculated for each target or structure, according to the following formula:

$$C_T=\Sigma C_{z1}+C_{z2}+C_{z3}+ \ldots C_{zn}, \text{ and}$$
$$C_S= \Sigma C_{z1}+C_{z2}+C_{z3}+ \ldots C_{zn,}$$

where C_S, and C_T, are the cost for each structure or zone, and C_{z1}, C_{z2}, C_{z3}, and C_{zn} are the costs calculated for each zone of the first, second, and third, through nth zone of each target or structure. The total cost for the change to the proposed beam distribution is then calculated, according to the following
formula:

$$C_{Total}=C_S+C_{T,}$$

where C_{Total}, is the total cost of the proposed change to the beam distribution.

In other words, if the region under the proposed CDVH curve, or pseudo-curve, is greater than the region under the desired CDVH curve, there is a high cost associated with the change to the proposed beam distribution. Thus, the system will reject the change that was made to the beams and will again attempt to change the beam weights to lower the total cost, according to conventional optimization techniques known in the art. Where target goals and structure limits conflict, beam changes will decrease the cost in the target while increasing the cost in one or more of the structures. A determination of whether or not that beam change is kept by the system depends upon the relative changes in the costs of the targets and structures.

By assigning different weights to different zones of the CDVH curves, different results can be obtained. Therefore, the weights are incorporated into the software with an outcome in mind, and the user must understand what kind of results the assigned weights will produce. One skilled in the art will be able to choose the desired weights without undue experimentation to achieve a desired outcome in the system. For instance, in one implementation of the invention, sparing of sensitive structures is preferred over treating the target in order to avoid complications which can result from the delivery of radiation. Sparing of sensitive structures is accomplished by delivering a dose distribution whereby the proposed

> structure CDVH curve, or structure pseudo-curve is equivalent to or better than the desired structure CDVH curve. In order to achieve this result, weights must be picked so that if a beam change is made that improves the proposed target CDVH curve, or target pseudo-curves, but worsens the proposed structure CDVH curves, or structure pseudo-curves, the change will be rejected. Therefore, high weights should be assigned to the structure zones that have been determined to be at risk for structural injury, such as zones S4, S5, and S8. The actual weights assigned are based upon clinical experience by one skilled in the art. These weights can then be programmed into the system so they can be used repeatedly to produce a desired outcome.

See, '283 Patent, Col. 13:1 – 14:10.

> The Prescription Panel step 802 allows the physician to input into the planning system the desired goal of the radiation therapy treatment, which is utilized in the plan optimization step 803.

Id., '283 Patent, Col. 10:31-34. See also, Col. 4:13 – 5:8 Col. 9:28- 12:67; and Col. 8:61-67.

The structure/algorithm can also be found in the figures depicted below:

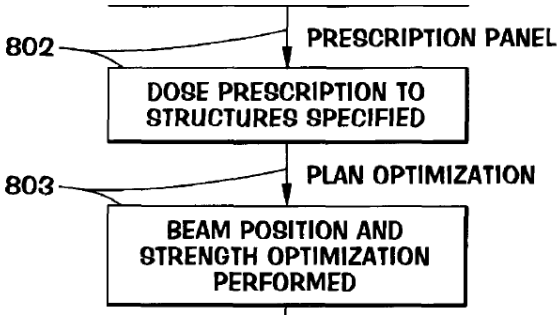
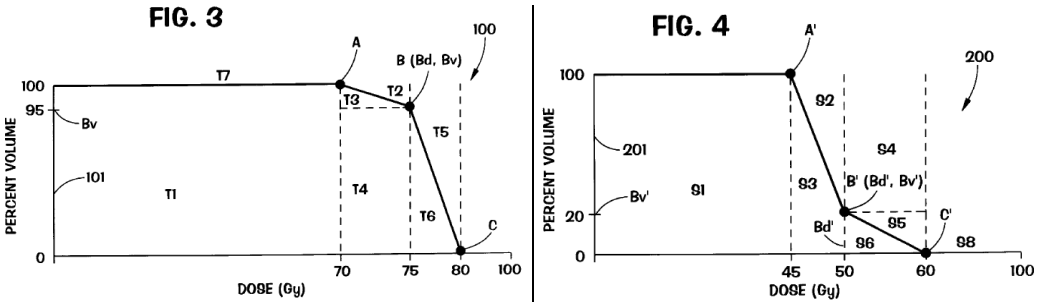
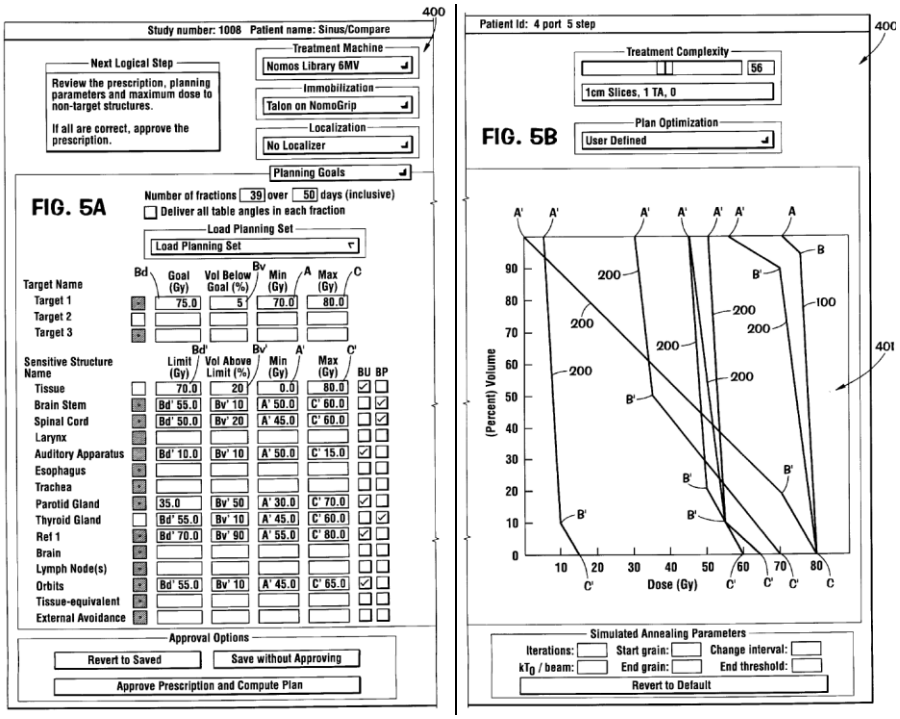


Figure 2





See also, '283 Patent, Col. 10:43 – 12:26.

6. **means for rejecting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and accepting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription** to obtain an optimized radiation beam arrangement

Best Medical's Proposed Construction

The parties agree that this term should be governed by 35 U.S.C. § 112(6).

Function

The function is rejecting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and accepting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam.

Structure

The corresponding structure includes a computer programmed to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam, and equivalents thereof.

The disclosed structure/algorithm is described in Col. 13:40 – 14:10 and Col. 14:47-58. See also, Col. 9:33-45 and Col. 12:27-34. See also, FIG. 2, step 803 ("PLAN OPTIMIZATION" and "BEAM POSITION AND STRENGTH OPTIMIZATION PERFORMED"), FIG. 5A ("Approve Prescription and Compute Plan") and FIG. 5B ("Plan Optimization," "User Defined" and "Simulated Annealing Parameters"). See also, Col. Col. 10:31-34 and 10:57 – 12:26.

The structure/algorithm described in the '283 Patent corresponding to the claimed function is set forth below:

> In other words, if the region under the proposed CDVH curve, or pseudo-curve, is greater than the region under the desired CDVH curve, there is a high cost associated with the change to the proposed beam distribution. Thus, the system will reject the change that was made to the beams and will again attempt to change the beam weights to lower the total cost, according to conventional optimization techniques known in the art.

> Where target goals and structure limits conflict, beam changes will decrease the cost in the target while increasing the cost in one or more of the structures. A determination of whether or not that beam change is kept by the system depends upon the relative changes in the costs of the targets and structures.
>
> By assigning different weights to different zones of the CDVH curves, different results can be obtained. Therefore, the weights are incorporated into the software with an outcome in mind, and the user must understand what kind of results the assigned weights will produce. One skilled in the art will be able to choose the desired weights without undue experimentation to achieve a desired outcome in the system. For instance, in one implementation of the invention, sparing of sensitive structures is preferred over treating the target in order to avoid complications which can result from the delivery of radiation. Sparing of sensitive structures is accomplished by delivering a dose distribution whereby the proposed structure CDVH curve, or structure pseudo-curve is equivalent to or better than the desired structure CDVH curve. In order to achieve this result, weights must be picked so that if a beam change is made that improves the proposed target CDVH curve, or target pseudo-curves, but worsens the proposed structure CDVH curves, or structure pseudo-curves, the change will be rejected. Therefore, high weights should be assigned to the structure zones that have been determined to be at risk for structural injury, such as zones S4, S5, and S8. The actual weights assigned are based upon clinical experience by one skilled in the art. These weights can then be programmed into the system so they can be used repeatedly to produce a desired outcome.

See, '283 Patent, Col. 13:40 – Col. 14:10.

> If the structure is a BU structure, then there is no increase in total cost associated with the beam change because zone S5 in the BU structure has been assigned a very low relative weight. Therefore, the system will accept that beam change. However, if the structure is a BP structure, then there is an increase in total cost associated with the beam change because zone S5 in the BP structure has been assigned a high relative weight. In such a case, the system will not accept the beam change that caused the increase in the total cost associated with the beam change and the system will attempt another beam change to reduce the total cost for the beam distribution.

Id., '283 Patent, Col. 14:47-58.

> The optimal beam arrangement is arrived at by computationally increasing the proposed beam weight iteratively, incorporating cost functions to ensure that an iterative change in the beam weight would not result in an

> unacceptable exposure to the volumes of tissue or other structures being subjected to the proposed dose. At each iteration, the dose distribution resulting from the proposed beam selection is compared to a prescribed dose for the tumor volume and surrounding tissue structures. If the increase or decrease in beam weights would lead to a greater correspondence to the desired prescription, change is accepted.

Id., '283 Patent, Col. 9:33-45.

> In the Plan Optimization step 803, the radiation plan optimization is a specific case of an inverse problem, where the goal is to determine the best way to achieve the dose prescription. A SARP technique is utilized to do this optimization by dividing the radiation delivery into a large number of small beams, each of which hit the target. The annealing cooling schedule utilized, fits into the class of FSA (Fast Simulated Annealing) techniques.

Id., '283 Patent, Col. 12:27-34.

> The Prescription Panel step 802 allows the physician to input into the planning system the desired goal of the radiation therapy treatment, which is utilized in the plan optimization step 803.

Id., '283 Patent, Col. 10:31-34. *See also* Col. 10:57 – 12:26.

The structure/algorithm can also be found in Figure 2, step 803 shown above and in Figures 5A and 5B depicted above.

IV. ESTIMATED LENGTH OF PRESENTATION

The Special Master has already entered an order regarding the length of presentation. Best Medical believes that the scheduled time will be sufficient to address all claim construction issues.

Respectfully submitted,

Dated: March 8, 2012

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CERTIFICATE OF SERVICE

I certify that on the 8th day of February, 2012, I served the foregoing via electronic mail only on the following:

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